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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,814

01/19/2005

Andrew Lennard Lewis

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/506,814	Applicant(s) LEWIS ET AL.	
	Examiner BLESSING M. FUBARA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 23-27 and 36-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 28-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/19/2005 & 8/29/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The examiner acknowledges receipt of response to election requirement filed 12/08/08. The examiner also acknowledges receipt of preliminary amendment filed 1/19/05. Claims 1-4, 6, 8-23, 25, 26 were amended, claim 27 was canceled and new claims 28-44 were added in the amendment filed 1/19/05. The examiner also acknowledges receipt of IDS filed 8/29/08.

Election/Restrictions

1. Applicant's election with traverse of claims 1-22 and 28-35, the zwitterionic monomer 2-methacroyloxyethyl phosphorylcholine (MPC) and ionic monomer 2-dimethylaminoethylmethacrylate used in Example 2 in the reply filed on 12/08/08 is acknowledged. The traversal is on the ground(s) that the prior art references, Storch, Bronich and Kabanov cited by the examiner do not disclose block copolymers having zwitterionic blocks. This is not found persuasive because while Storch, Bronich and Kabanov do not teach zwitterionic blocks, Stratford teaches polyion complex comprised of zwitterionic polymer and ionic monomer for delivery of pharmaceutically active agent agents and diagnostic agents.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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It is unclear how R^{23} in $COOR^{23}$ becomes R^2 in the claim when defining the R in the $COOR^{23}$

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-22 and 28-35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-43 of copending Application No. 10/542,333 in view of Storch et al. (WO 98/22517). The copending claims prepare the polyion block copolymer of the instant claims. The copending claims do not have ionic drugs. But Storch teaches that polyion block copolymers of the type claimed are capable of trapping heparin, negatively charged molecule (see the whole document with emphasis on the abstract, page 5, page 7). Therefore, taking the teaching of Storch in combination with the copending claims, multi-ionic compounds such as nucleic acid can be effectively trapped for later release.

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This is a provisional obviousness-type double patenting rejection.

6. Claims 1-22 and 28-35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 33-78 of copending Application No. 10/501,393 in view of Storch et al. (WO 98/22517). The copending claims teach the same polyion block copolymer that is associated with pharmacological or diagnostic active compound. Storch teaches that polyion block copolymers of the type claimed are capable of trapping heparin, negatively charged molecule (see the whole document with emphasis on the abstract, page 5, page 7). Therefore, taking the teaching of Storch in combination with the copending claims, multi-ionic compounds such as nucleic acid can be effectively trapped for later delivery.

This is a provisional obviousness-type double patenting rejection.

7. Claims 1-22 and 28-35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-50 of copending Application No. 10/544,113 in view of Storch et al. (WO 98/22517). The copending claims teach the same polyion block copolymer that is associated with pharmacological or diagnostic active compound. Storch teaches that polyion block copolymers of the type claimed are capable of trapping heparin, negatively charged molecule (see the whole document with emphasis on the abstract, page 5, page 7). Therefore, taking the teaching of Storch in combination with the copending claims, multi-ionic compounds such as nucleic acid can be effectively trapped for later delivery.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 20, 21, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Stratford et al. (WO 00/28920).

10. Stratford teaches the polymer of the type claimed (see the whole document with emphasis on the abstract and pages 6-13). These polymers have associated imaging agents (page 3, lines 5-13). The biologically active compound of claim 1 broadly reads on the bio-imaging compounds. Claims 20, 21, 33 and 34 are product by process claims and these claims are thus met by Stratford.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-22 and 28-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stratford et al. (WO 00/29481) in view of Storch et al. (WO 98/22517).

14. Stratford discloses polyion complex of the type claimed (see the whole document with emphasis on the abstract, structures on page 9, 10 and 11 corresponding to X, formula VII corresponds to claims 8, 43; see pages 16-27). Proteins such as fibrinogen are adsorbed onto the polymer (page 16). Stratford does not teach the presence of ionic compound in the polymer. But Storch teaches that polyion block copolymers of the type claimed are capable of trapping heparin, negatively charged molecule (see the whole document with emphasis on the abstract, page 5, page 7). Therefore, taking the teaching of Storch in combination with Stratford multi-ionic compounds such as nucleic acid can be effectively trapped for later delivery.

15. Claims 1-22 and 28-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stratford et al. (WO 00/29481) and Koulik et al. (US 6,270,788).

16. Stratford discloses polyion complex of the type claimed (see the whole document with emphasis on the abstract, structures on page 9, 10 and 11 corresponding to X, formula VII corresponds to claims 8, 43; see pages 16-27). Proteins such as fibrinogen are adsorbed onto the polymer (page 16). Stratford does not teach the presence of ionic compound in the polymer. Koulik teaches a terpolymer of MPC, alkyl acrylate and aminoethyl acrylate (column 6, lines 4-40) and biomolecules such as heparin (column 7, lines 15-22) and hormones, growth factors, nucleic acids, dyes, DNA and RNA that can be attached. Claims 21, 22, 33 and 34 are product by process claims. The terpolymer of Koulik and the copolymer of Stratford meet the polymer

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limitations of claims 1, 8-22, 28-34. The biomolecules meet the requirement of claims 2-6.

Therefore, taking the teachings of Stratford and Koulik, one having ordinary skill in the art at the time the invention was made would attach biomolecules to the MPC-acrylate block copolymers for anticipated delivery of these biomolecules.

17. No claim is allowed.

-Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
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